Docket No.: 12810-00682-US
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Rudolf Carolus Maria Barendse et al.

Application No.: 09/089,871 Confirmation No.: 3289

Filed: June 4, 1998 Art Unit: 1652

For: HIGH-ACTIVITY PHYTASE COMPOSITIONS Examiner: D. M. Ramirez

BRIEF ON APPEAL

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APPEAL BRIEF UNDER 37 C.F.R. § 41.37

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicants hereby appeal the Examiner's decision rejecting claims 18, 19, 21, 22, 24, 26-28, 31-35, 41-46, 48 and 50-52 as set forth in the Office Action of September 30, 2008.

As required under 37 C.F.R. § 41.37(a), this brief is filed within two months of the filing of the Notice of Appeal, which was filed on December 9, 2008, with the required fee authorization pursuant to § 41.20(b)(2).

I. REAL PARTY IN INTEREST

The real party in interest is BASF Aktiengesellschaft ("BASF"), the assignee of record.

II. RELATED APPEALS, INTERFERENCES, AND JUDICIAL PROCEEDINGS

A related appeal is Appeal No. 2006-0201 (U.S. Application Serial No. 10/125,272, now U.S. Patent No. 7,186,533). A copy of the Board decision issued in that case is provided under the Related Proceedings Appendix. The application in the 2006-0201 appeal is not in the same application family as the current application, but the 2006-0201 appeal shares the Real Party in interest with the present application and raised some similar issues to the present appeal. The 2006-0201 appeal therefore may have a bearing on the current appeal.

III. STATUS OF CLAIMS

Claims 1-38 were filed with the application. Claims 1-17, 29-30 and 36-38 were cancelled as directed to non-elected inventions. Claims 39 and 40 were added in the response filed August 11, 2000. Claims 41-52 were added with the filing of a Request for Continued Examination dated October 20, 2005. Claims 18, 19, 21, 22, 24, 26-28, 31-35, 41-46, 48 and 50-52 are presently pending and stand rejected. Claims 1-17, 20, 23, 25, 29, 30, 36-40, 47, and 49 are cancelled. The claims on appeal are claims 18, 19, 21, 22, 24, 26-28, 31-35, 41-46, 48 and 50-52. A copy of the appealed claims as they currently stand is provided in Section VIII as Appendix A.

IV. STATUS OF AMENDMENTS

An amendment to the claims was made with the filing of a Request for Continued Examination on August 4, 2008 and was entered by the Examiner. No subsequent amendments have been made. Accordingly, the claims on appeal are in the same form as those finally rejected on September 30, 2008.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Of the 23 claims on appeal, claims 18 and 19 are independent. Claim 18 and the claims dependent therefrom (claims 31-35 45, 46, 48, and 50-51) and claim 19 and the claims dependent therefrom (claims 21, 22, 24, 26-28 and 41-44) will be argued separately.

Briefly, claim 18 recites a high activity phytase-containing granulate (p. 2, ll. 28-31; p. 3, ll. 6, 24-28; p. 6, ll. 10-11) having increased pelleting stability (p. 2, ll. 32-33; p. 3, ll. 1-2; example 5 at p. 18, l. 13 to p. 19, l. 30; and example 10 at p. 22, ll. 18-29) comprising the steps of:[1]

(a) providing a non-fibrous solid carrier comprising at least 15% (w/w) of starch (p. 6, ll. 10-12, 19-20 (carrier); p. 7, ll. 1-2, 15-16 (starch));

(b) providing an aqueous liquid comprising a phytase at a concentration of at least 14,000 FTU per gram of aqueous liquid; (p. 3, l. 25; p. 4, ll. 19-24; p. 5, l. 33; p. 6, l. 1); and

(c) mixing the solid carrier and the aqueous liquid to form a granulate having a phytase activity of at least 6000 FTU per gram (p. 13, ll. 11-16);

wherein said granulate is prepared by extrusion (p. 8, ll. 23-28; p. 9, ll. 10-16).

Claim 19 recites a granulate having a phytase activity of at least 6000 FTU per gram (p. 13, ll. 11-16) and having increased pelleting stability (p. 2, ll. 32-33; p. 3, ll. 1-2; example 5 at p. 18, l. 13 to p. 19, l. 30; and example 10 at p. 22, ll. 18-29) comprising dried granules (p. 9, ll. 25-29) formed from an aqueous liquid comprising a phytase at a concentration of at least 14,000 FTU per gram of aqueous liquid (p. 3, l. 25; p. 4, ll. 19-24; p. 5, l. 33; p. 6, l. 1) and a non-fibrous solid carrier (p. 6, ll. 10-12, 19-20) which comprises at least 15% (w/w) of starch (p. 7, ll. 1-2, 15-16) and at least one divalent cation (p. 10, ll. 15-27).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The grounds of rejection for review on appeal are as follows:

A. Does the recitation of "increased pelleting stability" render claims 18 and 19 and the claims dependent therefrom (claims 21, 22, 24, 26-28 and 41-44 dependent on claim 19 and

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[1] Upon further review, if necessary, Applicants would be prepared to amend the claim for clarification as follows (amendment underlined):

18. A high activity phytase-containing granulate having increased pelleting stability prepared by a process comprising the steps of:

(a) providing a non-fibrous solid carrier comprising at least 15% (w/w) of starch;

(b) providing an aqueous liquid comprising a phytase at a concentration of at least 14,000 FTU per gram of aqueous liquid; and

(c) mixing the solid carrier and the aqueous liquid to form a granulate having a phytase activity of at least 6000 FTU per gram;

wherein said granulate is prepared by extrusion.

claims 31-35, 45, 46, 48, and 50-51 dependent on claim 18) indefinite and therefore unpatentable under 35 U.S.C. § 112, second paragraph?

B. Are claims 18, 19, 21, 24, 26-28, 31-35, 41-44, 48 and 50-52 unpatentable under 35 U.S.C. § 103(a) as being obvious over Nielson *et al.* WO 95/28850 ("Nielson") in view of Ghani U.S. Patent No. 6,120,811 ("Ghani")?

C. Are claims 22 and 46 unpatentable under 35 U.S.C. § 103(a) as being obvious over Nielson in view of Ghani and in further view of Markussen *et al.* U.S. Patent No. 4,106,991 ("Markussen")?

D. Are claims 18, 19, 21, 22, 24, 26-28, 31-35, 41-46, 48 and 50-52 unpatentable under 35 U.S.C. § 103(a) as being obvious over Nielson in view of Ghani, and in further view of Haarasilta GB 2-139868 ("Haarasilta")?

VII. ARGUMENT

A. The Recitation Of "Increased Pelleting Stability" Does Not Render the Claims Indefinite.

Claims 19, 21, 22, 24, 26-28, and 41-44

Claims 18, 19, 21, 22, 24, 26-28, 31-35, 41-46, 48, and 50-52 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite in the recitation of "increased pelleting stability." Applicants strongly disagree.

Applicants have repeatedly stated that "increased pelleting stability" refers to ***residual phytase activity*** in the pellet after the pelleting process. The Examiner rejects this interpretation as not supported by the prior art and as contrary to the more apparent interpretation, "i.e. stability of the pellet after the pelleting process" such as higher structural stability. Final Office Action, Sept. 30, 2008, pp. 3-4 . The Examiner finds that the specification does not provide a definition of the term. Appellants respectfully disagree.

"The test for definiteness under 35 U.S.C. 112, second paragraph, is whether 'those skilled in the art would understand what is claimed ***when the claim is read in light of the specification***.'" (M.P.E.P. § 2173.02, emphasis added). If one skilled in the art is able to ascertain the meaning of the terms in light of the specification, 35 U.S.C. 112, second paragraph, is satisfied. *Id.* Furthermore, the specification should be relied on for more than just explicit lexicography or clear disavowal of claim scope to determine the meaning of a claim term when applicant acts as his or her own lexicographer; the meaning of a particular claim term may be defined by implication, that is, according to ***the usage of the term in context in the specification***. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1321 (Fed. Cir. 2005) (en banc) ("Even when guidance is not provided in explicit definitional format, the specification may define claim terms by implication such that the meaning may be found in or ascertained by a reading of the patent documents.") (citations omitted); *Irdeto Access, Inc. v. Echostar Satellite Corp.*, 383 F.3d 1295, 1301 (Fed. Cir. 2004) ("when a patentee uses a claim term throughout the entire patent specification, in a manner consistent with only a single meaning, he has defined that term 'by implication'.") (citations omitted).

Here, the use of "increased pelleting stability" in the specification makes abundantly clear to the ordinary skilled reader what is meant by the term. Specifically, Example 5 entitled "High Activity Phytase Stability Tests" uses the term "pelleting stability" throughout, such as at page 18, line 16, ". . . and the pelleting stability of these samples were tested," and at page 19, line 15 "Comparison of pelleting stabilities." The "Results of the pelleting tests" are reported as percent of enzyme activity yield after pelleting. Thus, the specification implies that pelleting stability refers to residual enzyme activity.

Additionally, Example 10 shows in context that "pelleting stability" means residual phytase activity:

> The results of this test for ***residual activity*** were: 63(A); 66(B) and 72%(C) respectively for the original 610; 4170; 6830 and FTU/g samples. This shows that even with similar activities (B and C) the highest activity formulation (C; 6830 FTU/g, of the invention) gave a much higher ***pelleting stability***. This was 6% higher than for (comparative) Sample B, remarkable as only a 3% increase was

> observed (from A to B) with a very large increase in activity (610 to 4170 FTU/g). (See specification, p. 22, ll. 24-29; emphasis added)

Clearly, the specification uses pelleting stability to refer to residual phytase activity.

The Examiner argues that "pelleting stability" has the apparent meaning of higher structural stability. Yet nowhere in the application is "pelleting stability" exemplified as relating to a structural characteristic. Therefore, according to the strictures of claim construction, this allegedly apparent meaning should be given no weight.

The Examiner also argues that when more than one reasonable interpretation exists, Applicants should provide a clear statement of how Applicants wish the term to be interpreted. Yet Applicants have done this. They clearly stated that residual phytase activity was the intended definition in the Amendment in Response to Non-Final Action dated January 24, 2008. In that response, Appellants showed by declaration both where the specification supports this meaning and where multiple references show retention of enzyme activity as related to pelleting stability. The Expert Declaration under 37 C.F.R. 1.132, signed by Dr. Lutz End (attached as Appendix B; hereinafter the 'Declaration'), discusses what the term means by concluding from the specification and the knowledge of one skilled in the art at the time what "increased pelleting stability" meant in the context of the invention.

In the Declaration, Dr. Lutz End, Head of Formulation and Nutrition R&D in the Care Chemicals Division at BASF SE, declares in paragraph 3:

> "I hereby declare that the skilled artisan, at the time of the invention, using the teachings of the specification would have understood that the term "pelleting stability" was intended to refer to residual phytase activity in the pellet after the pelleting process, and not the structural stability of the pellet itself."

Dr. End points out clearly and in detail the teachings in the specification as to "increased pelleting stability" that are summarized above (see Declaration, Appendix B, paragraphs 3-9). Dr. End additionally presents numerous articles showing concern with enzyme stability during pelleting at the time of filing (see Declaration, Appendix B, paragraphs 10-20). Furthermore, Appellants through Dr. End's declaration have clearly stated the meaning they intend for the claim term:

> "20. Accordingly, based on the teachings of the specification and the knowledge and methods known at the time of the invention, the skilled artisan would have appreciated the term "increased pelleting stability" was intended to refer to a higher than normal post-pelleting phytase activity in the pellet, and not to the structural stability of the pellet itself." (see Declaration, Appendix B, at paragraph 20).

The Examiner further contends that even if it is assumed that the term "pelleting stability" as used in the claims is definite, the term "increased pelleting stability" is unclear and confusing in the absence of a basis for comparison. Appellants respectfully disagree.

Relative terminology is permissible in claims. MPEP § 2173.05(b); *Seattle Box Co.,v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). See also *In re Mattison*, 509 F.2d 563, 184 USPQ 484 (CCPA 1975) (holding that the limitation "to substantially increase the efficiency of the compound as a copper extractant" was definite in view of the general guidelines contained in the specification). Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification.

When a term of degree is presented in a claim, first a determination is to be made as to whether the specification provides some standard for measuring that degree. If it does not, a determination is made as to whether one of ordinary skill in the art, in view of the prior art and the status of the art, nevertheless would be reasonably apprised of the scope of the invention. See MPEP § 2173.05(b). The Examiner has not made the requisite determinations and as such has not properly established a basis for a finding of indefiniteness.

The specification provides a standard for measuring "pelleting stability" in Example 5 (p. 18-19) and in Example 10 (p. 21-22). Example 5 is entitled "High Activity Phytase Stability Tests" and explains that "[t]o demonstrate that a higher enzyme concentration (in granules made using the high activity phytase liquid) gives a ***higher pelleting stability***, granules with an increasing enzyme concentration were made and the ***pelleting stability*** of these samples were tested." (p. 18, ll. 14-17; emphasis added). Samples A, B, and C, which were compared, had pre-pelleting phytase activities of 610 FTU/g, 4170 FTU/g, and 6830 FTU/g (p. 18 l. 18 through p. 19 l. 14). The final section of Example 5 entitled "Comparison of the pelleting stabilities" first describes the preparation of pellets from the sample granules A, B, and C explaining that the

process was typical for the feed industry to obtain pellets (p. 18, ll. 15-22). Dr. End in his Declaration further explains that after the pellets were dried the post-pelleting yield was calculated by comparing the residual phytase activity of each sample with the corresponding pre-pelleting activity (see Declaration, Appendix B, at paragraph 8). The resulting post-pelleting phytase activity yields are presented as percentages in Table 2 under the column entitled "Enzyme yield after pelleting," which shows that the low-phytase comparative sample A had a less than 17% yield, whereas the high phytase comparative samples B and C had significantly higher yields of 37% and 48% respectively (p. 19, ll. 26-30, Table 2). The results of the pelleting stability testing described in Table 2 are summarized as follows ". . . granules with the highest enzyme concentration had much higher pelleting stability." (p. 19, ll. 24-25). The results shown in Table 2 are "Enzyme yield after pelleting." Thus the term "pelleting stability" is used in reference to the results of Table 2 which shows "Enzyme yield after pelleting."

Furthermore, Example 10 demonstrates that the highest activity formulation when mixed with feed then pelleted resulted in a much higher pelleting stability based on the residual phytase activity (p. 22, ll. 24-27).

Even if one were to disregard this clear teaching in the specification of how to measure "increased pelting stability," the prior art and the status of the art would reasonably apprise the skilled person on how to measure the increase. Dr. End summarizes the understanding in the art from the references discussed in the Declaration as follows:

> "19. Thus, based on the prior art literature, there is a clear sense that each enzyme has its own pattern of thermal inactivation as a result of feed pelleting, also known as a 'stability curve'. Any modifications to the enzyme itself and/or to the process of granulation that have a tendency to shift the stability curve to the right, i.e., toward a higher temperature tolerance, would be understood by a skilled artisan to result in an 'increased pelleting stability' as recited in claims 18 and 19 of the present application." (See Declaration, Appendix B, paragraph 19).

In sum, not only does the specification inform the skilled person how to determine "increased," but even if the skilled person needed to look elsewhere, he or she would find a means of measuring "increased" in the prior art and the status of the art. Thus, under the analysis presented in MPEP § 2173.05(b), "increased pelleting stability" is definite and meets the requirements of 35 USC § 112, second paragraph.

Additionally, the Board of Patent Appeals and Interferences recently decided an appeal in a related application and had no difficulty interpreting "pelleting stability" in a manner consistent with the discussion above: "The specification reports that coating the granules with polyethylene glycol (PEG)... 'provide[s] a good pelleting stability of the granule,' i.e., results in less loss of enzyme activity during pelleting" (Appeal No. 2006-0201 in Application Serial No. 10/125,272, now U.S. Patent No. 7,186,533; see Appendix C, p. 2, third paragraph; emphasis added).

Accordingly, Appellants respectfully submit that the claims are clear and definite and urge that the rejection be reversed.

Claims 18, 31-35, 45, 46, 48 and 50-52

As with claim 19 and its dependent claims discussed above, claim 18 and its dependent progeny were similarly rejected as indefinite in reciting "increased pelleting stability."

Claim 18 relates to a high activity phytase-containing granulate having increased pelleting stability prepared by a process which comprises mixing a non-fibrous solid carrier comprising at least 15% (w/w) of starch and an aqueous liquid comprising a phytase at a concentration of at least 14,000 FTU per gram of aqueous liquid to form a granulate having a phytase activity of at least 6000 FTU per gram and wherein the granulate is produced by extrusion.[2] The high activity phytase-containing granulate thus has phytase activity of at least 6000 FTU per gram and has increased pelleting stability.

For the same reasons as explained above regarding claims 19, 21, 22, 24, 26-28, and 41-44, "increased pelleting stability" does not render claims 18, 31-35, 45, 46, 48 and 50-52 indefinite and reversal of the rejection is urged.

[2] See footnote 1 above.

B. The Claims Are Non-Obvious Over Nielson In View Of Ghani.

Claims 19, 21, 24, 26-28, and 41-44

Claims 18, 19, 21, 24, 26-28, 31-35, 41-45, 48 and 50-52 were rejected under 35 U.S.C. § 103(a) as being obvious over Nielson *et al.* WO 95/28850 ("Nielson") in view of Ghani U.S. Patent No. 6,120,811 ("Ghani").

Claims 22 and 46 were rejected under 35 U.S.C. § 103(a) as being obvious over Nielsen in view of Ghani and further in view of Markussen *et al.* ("Markussen").

Claims 18-19, 21-22, 24, 26-28, 31-35, 41-46, 48, 50-52 were rejected under 35 U.S.C. 103(a) for obviousness over Nielsen in view of Ghani and further in view of Haarasilta.

The Examiner bases all these obviousness rejections mainly on the following: (1) on not giving patentable weight to the term "increased pelleting stability"; (2) on alleging that Nielsen alone teaches a granulate that has at least 6000 FTU/gram; and (3) on alleging that Nielsen teaches granulates that inherently have increased pelleting stability. Appellants strongly disagree with the Examiner's interpretation of the term and the characterization of the references for the reasons already of record and additionally for the following reasons.

1. "Increased Pelleting Stability" Should Be Given Patentable Weight.

Claim 19 of the present application relate to granulates having high phytase activity of at least 6000 FTU per gram and having increased pelleting stability. The granulate comprises dried granules formed from an aqueous liquid comprising a phytase at a concentration of at least 14,000 FTU per gram of aqueous liquid and a non-fibrous solid carrier which comprises at least 15% (w/w) of starch and at least one divalent cation.

Appellants' inventive, highly active granulate overcomes enzyme stability problems arising from high temperatures used in pelleting for feed processing. (p. 2, ll. 31-33). Appellants' granulates provide a cost effective high activity granulate which has surprisingly shown marked increase in pelleting stability during the pelleting process used to make animal feed pellets. (p. 4, ll. 3-8; p. 11, ll. 22-30). Surprisingly, the high activity phytase granulates of

Appellants' invention have high phytase activity even after having been pelleted. (p. 2, l. 31 through p. 3, l. 3, Example 5).

Because the Examiner found "increased pelleting stability" indefinite, she did not give it any patentable weight. For the clear reasons presented supra, however, the term is definite and should be given patentable weight.[3]

Once "increased pelleting stability" is given patentable weight, the obviousness rejection falls apart. None of the references cited by the Examiner in any of the obviousness rejections discusses pelleting stability or discusses a connection between high phytase activity and increased pelleting stability. Moreover, the Examiner has acknowledged that neither Nielson, Ghani, Markussen, nor Haarasilta discuss pelleting stability and that Nielsen additionally does not teach extrusion (see Office Action dated July 27, 2007, p. 6, item 14). Thus, by the Examiner's own statement, Nielson, Ghani, Markussen, and Haarasilta, alone or in combination, do not disclose or teach all the claim limitations and as such a *prima facie* case of obviousness has not been established. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993) (the examiner bears the initial burden of establishing *prima facie* obviousness); *In re Lowry*, 32 F.3d 1579, 1582, 32 USPQ2d 1031, 1034 (Fed. Cir. 1994) (to support a *prima facie* conclusion of obviousness, the prior art must disclose or suggest all the limitations of the claimed invention); see also *Ex parte Alexander*, 86 USPQ2d 1120, 1122 (BPAI 2007) (where the Board reversed the obviousness rejection in part because the Examiner had not identified all the elements of the claim).

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[3] Although arguably "increased pelleting stability"appears in the preamble, because the term gives "life, meaning, and vitality" to the claim, it further defines the claimed invention, and has been the basis for numerous arguments throughout prosecution to distinguish the art, the term should be given patentable weight despite its arguable preamble location. MPEP § 2111.02 (clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention.); *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999) ("If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim."); also *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951) (where the preamble reciting "An abrasive article" was deemed essential to point out the invention defined by claims to an article comprising abrasive grains and a hardened binder and the process of making it. The court stated "it is only by that phrase that it can be known that the subject matter defined by the claims is comprised as an abrasive article. Every union of substances capable *inter alia* of use as abrasive grains and a binder is not an 'abrasive article.'").

The Examiner also argues that limitations appearing in the specification but not recited in the claims should not be read into the claims (final Office Action dated September 30, 2008, p. 8, ll. 5-13; emphasis added). Applicants have not imported any limitations into the claims because the term "increased pelleting stability" is already recited in the claims. The interpretation of the claims must be reasonable in light of the specification, and must not be inconsistent with the specification. *In re American Academy of Science Tech Center*, 367 F.3d 1359, 1369 (Fed. Cir. 2004); *In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1989); MPEP § 2111.01. The Examiner's interpretation relating to structural stability would not be reasonable in the context of the specification which is silent regarding structural stability and as such would be inconsistent with its teachings. As explained above, "increased pelleting stability" refers to residual phytase activity in the pellet after the pelleting process.

The Examiner also argued that even if the term were given patentable weight and given the interpretation of "higher phytase activity in the granulate after pelleting", the granulate of Nielsen alone would allegedly meet this limitation. Applicants strongly disagree that the additive of Nielsen teaches or suggests the claimed granulate for the reasons explained in detail below.

2. Nielsen Does Not Teach Or Suggest The Claimed Granulate.

The Examiner contends "that granules that have at least 6000 FTU/gram are taught by Nielsen alone" (Final Office Action dated September 30, 2008, p. 7, l. 20). The Examiner further argues that the granulate of Nielsen would inherently have enhanced phytase activity because it allegedly meets the phytase activity limitation. Applicants strongly disagree with the Examiner's characterization of Nielsen and the Examiner's application of inherency principles in the context of an obviousness rejection.

The Examiner alleges that "granules that have at least 6000 FTU/gram are taught by Nielsen alone." Applicants disagree that Nielsen teaches a granulate having a phytase activity of at least 6000 FTU/gram as required by the claims.

Nielsen teaches a method for solubilizing proteins in a vegetable protein source, which comprises treating the vegetable protein source with one or more phytase enzymes and treating

the vegetable protein source with an efficient amount of one or more proteolytic enzymes. (Nielsen, p. 3, ll. 3-7). Although the Examiner refers to Nielsen as allegedly disclosing a granulate of at least 6000 FTU/gram, the additives of Nielsen are described in broad terms by broad ranges of enzymes concentrations and activity. Nielsen describes broad ranges of an amount of phytase efficient for improving solubility of vegetable protein, such as from 2 to about 50000 FYT per kg of vegetable protein source, with a most preferred range from about 100 to about 10000 FYT per kg of vegetable protein source (Nielsen, p. 7, ll. 11-13). Nielsen also describes generally broad ranges of the amount of phytase activity in an animal feed additive such as in the range from 200 to about 50000 FYT per gram of total composition with the most preferred range from about 2000 to about 6000 FYT per gram of the total composition (Nielsen, p. 11, ll. 27-30, p.12, ll.1-2).

These broad ranges fail to teach the claimed limit of at least 6000 FTU per gram granulate for several reasons. First, Nielsen calculates the amount of phytase activity based on total composition of a feed composition containing high amounts of proteinaceous vegetables. In contrast, the present invention requires phytase activity of at least 6000 FTU per gram of granulates which have increased pelleting stability and comprise a non-fibrous solid carrier comprising starch and an aqueous liquid comprising phytase. The phytase activity in Nielsen is not described in the context of granulates as required in the present claims but rather in the context of total composition. Thus, Nielsen does not teach a granulate having a phytase activity of at least 6000 FTU/gram as required by the claims. Because Nielsen alone is relied on for allegedly teaching a granulate having a phytase activity of at least 6000 FTU/gram and because Nielsen does not teach such a granulate, the Examiner has not met her burden of establishing a *prima facie* case of obviousness.

Second, even if one were to accept these ranges as indicating phytase activity in granulates, these broad ranges act as a genus from which the particular species – at least 6000 FTU/gram – is not taught because there is no suggestion of its surprising properties of improved pelleting stability. See Table 2 on p. 19 of the present specification showing the surprising improvement in enzyme activity in granulates having 6,830 FTU/g phytase prior to pelleting compared to granulates having 610 and 4,170 FTU/g phytase activity prior to pelleting.

The Examiner also relies on Example 3 in Nielsen as allegedly teaching high activity phytase granulates. Although Nielsen refers to several enzyme concentrations throughout the specification as just explained, the alleged disclosure of a granulate of at least 6000 FTU/gram is apparently found in Example 3 at page 16-17 of Nielsen. Example 3 of Nielsen compares the effect of an animal diet with and without phytase. One group of pigs was fed a specified diet and a second group of pigs was fed "the same diet but with addition of phytase 20.3 g/100 kg feed of Phytase Novo™ (an *Aspergillus* phytase, 7370 FYT/g)." (emphasis added; see Nielsen, Example 3, pp. 16-17). Thus, Nielsen suggests that for their animal diet with phytase, the phytase was applied to an already pelleted diet. Therefore, Example 3 of Nielsen does not teach or suggest a **granulate** having at least 6000 FTU/gram, but rather **pellets without any enzymes**, where the enzyme was added to the **pellet** only after pelleting. Thus, the alleged teaching in Nielsen of a granulate of at least 6000 FTU/gram cannot have increased pelleting stability because the enzyme was applied to a **pellet** after pelleting.

Furthermore, even assuming *arguendo* that the claimed granulate corresponds to the final feed in Nielsen Example 3, the phytase activity taught in Example 3 of Nielsen would only be 1.496 FYT/g of feed (*i.e.* 7370/g x 20.3 g/100 kg feed, then convert to g of feed), which is well below the claimed range of at least 6000 FTU/g.[4] Thus, the claimed enzyme level is not found in Example 3 of Nielsen.

The Patent Office argues that Example 3 in Nielsen is one of the many teachings regarding the use of phytase in animal feed and asserts that "Nielsen specifically and explicitly teaches an animal feed additive which is a granulated enzyme product" concluding that this teaches granules already having phytase in them (Final Office Action dated September 30, 2008, p. 7, ll. 7-8). However, this general teaching of a "granulated enzyme product" in Nielsen still does not teach or suggest a granulate having improved pelleting stability and having a phytase activity of at least 6000 FTU per gram. There is nothing in Nielsen to lead one skilled in the art to select the particular phytase activity of the granulate as claimed from the broad ranges of phytase activity directed to total composition or feed compositions. Furthermore, the Examiner

[4] Although Appellants' specification uses "FTU" and Nielsen uses "FYT", both refer to the same activity measure: the amount of enzyme that under standard conditions liberates 1 micromol of phosphate per minute from phytate substrate. See present application at p. 4 ll. 19-24 and Nielsen at p. 12, paras. 3-5.

cannot selectively pick and choose from the disclosed parameters without proper motivation as to a particular selection. *In re Mills*, 916 F.2d 680, 682, 16 USPQ2d 1430 (Fed. Cir. 1990); *In re Fritch*, 23 USPQ2d 1780 (Fed. Cir. 1992) (The mere fact that a reference may be modified to reflect features of the claimed invention does not make the modification, and hence the claimed invention, obvious unless the prior art suggested the desirability of such modification.). The fact that a claimed species or subgenus may be encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness. *In re Baird*, 16 F.3d 380, 382-383 (Fed. Cir. 1994) (disclosure of dissimilar species can provide teaching away; "[t]he fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious.").

The Examiner also relies on Nielsen for allegedly teaching "increased pelleting stability" based on inherency. The Examiner has asserted that "[i]t is reiterated herein that the "inherency" argument made is in reference to a property/characteristic required in the claimed product . . .." (see Office Action dated May 6, 2008, p. 5, item 13, last sentence). In responding to Appellants arguments regarding inherency in the Final Office Action, the Examiner further argues "that inherency can be used in the instant case because inherency is not being used to provide motivation to combine the references but to show Applicant's asserted property for the claimed pellets . . . is inherent to the pellet of Nielsen in view of the fact that the granulate of Nielsen alone has at least 6000 FTU/gram" (Final Office Action dated September 30, 2008, p. 6, last paragraph; emphasis added; also at p.8, ll. 17). Applicants strongly disagree with the applicability of inherency in the context of the present obviousness rejection and that Nielsen inherently teaches or suggests increased pelleting stability or that Nielsen teaches or suggests the granulate as claimed.

To establish that a missing claim limitation is inherent, the Examiner must provide rationale or evidence making "clear that the missing descriptive matter is ***necessarily present*** in the thing described in the reference." *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999). As such, inherency may not be established by probabilities or possibilities and the mere fact that a certain thing ***may result*** from a given set of circumstances is not sufficient. *Id. See also In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993) ("The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish inherency of that result or

characteristic."). This requirement that rationale or evidence be provided by the Examiner ***is separate and in addition to*** the requirement that the Examiner base the rejection on a reference that teaches a product appearing to be substantially identical to the claimed product. *See* MPEP 2112(V).

Inherency is inapplicable in the present case first because the Examiner has not made clear that the missing feature of "increased pelleting stability" is ***necessarily present*** in the additives taught by Nielsen.

As explained above, the amount of phytase activity in Nielsen is described in the context of the total composition described as feed compositions containing high amounts of proteinaceous vegetables and not as it relates to the additives themselves. Phytase activity as it relates to granulates is different than phytase activity relating to the total composition or feed composition. For example, the specification and original claims recite that the granulates can be mixed with feed substances/ingredients and incorporated into animal feed (for example, p. 3, ll. 8-9, p. 13, ll. 16-27, and original claims 29, 30, 34). Thus, Nielsen does not teach a granulate having a phytase activity of at least 6000 FTU/gram as required by the claims. Furthermore, Nielsen does not mention pelleting stability let alone recognize that the increased pelleting stability was a function of the particular claimed activity of the granulate, and therefore the parameter optimized was not recognized in the art to be a result-effective variable.

Because there is no disclosure of a granulate of at least 6000 FTU/gram and because the enzyme is added to an already pelleted animal diet, the Examiner has not established that the reference teaches a product appearing to be substantially identical to the claimed product let alone that the missing descriptive matter is ***necessarily present*** in the thing described in the reference as required for a showing of inherency.

Furthermore, "[t]he inherency of an advantage and its obviousness are entirely different questions." *In re Naylor*, 369 F.2d 765, 768 (CCPA 1966). "The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient [to establish inherency]." *See In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993). "That which may be **inherent is not necessarily known. Obviousness cannot be predicated on what is unknown**" even if the inherency of a certain feature is later established. (emphasis added). *See In re Rijckaert*, 9 F.3d at 1534; *see*

also In re Shetty, 566 F.2d 81, 86 (CCPA 1977) and *In re Naylor*, 369 F.2d 765, 768 (CCPA 1966). Because Nielsen does not teach or disclose the claimed granulate and does not mention pelleting stability, there is no basis for finding obviousness.

In responding to Appellants previous arguments regarding inherency in the Final Office Action, the Examiner also argues "that inherency can be used in the instant case because inherency is not being used to provide motivation to combine the references but to show Applicant's asserted property for the **claimed pellets** . . . is inherent to **the pellet of Nielsen** in view of the fact that the granulate of Nielsen alone has at least 6000 FTU/gram" (Final Office Action dated September 30, 2008, p. 6, last paragraph; emphasis added). Contrary to the Examiner's assertion, Applicants are claiming high activity phytase-containing **granulates** not **pellets**. As explained above, the pellet in Example 3 of Nielsen cannot have increased pelleting stability as a result of an alleged teaching of a granulate having at least 6000 FTU/gram, because the enzyme was applied to a **pellet after pelleting**. In contrast, for the present phytase-containing granulate to have increased pelleting stability as claimed, the phytase is added prior to pelleting.

The Examiner further attempts to distinguish *In re Antonie* by contending that the present rejection does not rely on inherency to show a suggestion to combine references. Appellants strongly disagree.

Contrary to the Examiner's assertion, the facts *In re Antonie* are analogous to the facts presented here. See *In re Antonie*, 559 F.2d 618, 619-620 (CCPA 1977). In *In re Antonie*, the claimed invention related to a wastewater treatment device having a tank volume to contractor area of 0.12 gal./sq. ft. This ratio resulted in the claimed devices' maximized treatment capacity. The single prior art reference did not disclose this ratio, and no showing was made that the embodiments in the prior art had the ratio. The Examiner reasoned that a skilled person would be motivated to experiment and reach the ratio. The Court reversed, stating that the claimed ratio would not have been recognized from the prior art. Furthermore, experiments of the parameters would not have been obvious from the art. Similarly here, Nielsen does not teach a specific example of a granulate within the claims and does not disclose anything that would lead one to identify that granulates with at least 6000 FTU per gram would improve pelleting stability.

Thus, like *In re Antonie* neither the element is disclosed nor is there a suggestion to modify the reference to obtain the claimed element. Thus, the obviousness rejection should be reversed consistent with the holding in *In re Antonie*.

3. Ghani does not remedy the deficiencies of Nielsen

The Examiner acknowledges that Nielsen does not teach extrusion of the granulate, does not teach a carrier comprising 15% (w/w) starch, does not teach at least one divalent cation, or a gel-forming or water insoluble compound (Office Action dated July 27, 2007, p. 5, item 12; p. 6, item 14). The teachings of Ghani, Markussen and Haarassilta were introduced as references which allegedly render obvious limitations other than the level of phytase activity in the granulates over the teachings of Nielsen as stated in the Final Office Action (Final Office Action dated September 30, 2008, p. 8, ll. 1-2).

The Examiner relies on Ghani for allegedly teaching a carrier containing 90% soy flour and 10% corn syrup. However, this disclosure does not teach or suggest a non-fibrous solid carrier which comprises at least 15% (w/w) of starch as required by the claims. In addition, the Examiner acknowledges that Ghani does not discuss pelleting stability with regard to phytase granulates (Office Action dated July 7, 2007, p. 6, item 14) and does not teach a specific divalent cation (Office Action dated May 18, 2006, p. 7). Therefore, Ghani does not remedy the deficiencies of Nielsen. Furthermore, these references do not teach, suggest, or recognize that increased pelleting stability is a function of the high activity phytase-containing granulate as claimed. Because Ghani does not remedy the deficiencies of Nielsen, Nielson and Ghani, alone or in combination, do not disclose or teach all the claim limitations, and as such a *prima facie* case of obviousness has not been established for this additional reason.

Further, assuming *arguendo* that a *prima facie* case of obviousness had been established, a *prima facie* case of obviousness is rebuttable by evidence that the claimed invention possesses unexpectedly advantageous or superior properties. See *KSR Int'l Co. v. Teleflex, Inc*, 127 S.Ct. 1727; 82 USPQ2d 1385 (2007), *In re Papesch*, 315 F.2d 382 (CCPA 1963). Appellants' inventive, highly concentrated granulate overcomes enzyme stability problems arising from high temperatures associated with pelleting during feed processing while retaining high enzyme activity (p. 2, ll. 31-33). Appellants' granulates provide a cost effective high activity granulate

which has surprisingly shown marked increase in pelleting stability during the pelleting process in the preparation of animal feed. (p. 4, ll. 3-8; p. 11, ll. 22-30). Surprisingly, the high activity phytase granulates of Appellants' invention have high phytase activity even after having been pelleted as explained above (p. 2, l. 31 through p. 3, l. 3), and as exemplified in Examples 5 and 10 (see also attached Declaration, Appendix B, at paragraphs 3 through 9 further explaining Example 5 and its teachings). For this additional reason, the obviousness rejection should be reversed.

For at least these reasons, reversal of the obviousness rejections is respectfully requested for claim 19 and the claims dependent therefrom. *See In re Fine,* 837 F.2d 1071, 1076 (Fed. Cir. 1988) (holding that if an independent claim is nonobvious then any claim dependent therefrom is nonobvious).

Claims 18, 31-35, 45, 48, and 50-52

Claims 18, 19, 21, 24, 26-28, 31-35, 41-45, 48, and 50-52 were rejected under 35 U.S.C. § 103(a) as being obvious over Nielson in view of Ghani.

Claim 18 relates to a high activity phytase-containing granulate having ***increased pelleting stability*** prepared by a process which comprises mixing a non-fibrous solid carrier comprising at least 15% (w/w) of starch and an aqueous liquid comprising a phytase at a concentration of at least 14,000 FTU per gram of aqueous liquid to form a ***granulate*** having a ***phytase activity of at least 6000 FTU per gram*** and wherein the granulate is produced by extrusion.[5]

Claim 18 and the claims dependent therefrom are not obvious over Nielsen in view of Ghani. The explanations above for claim 19 and the claims dependent therefrom regarding patentable weight of "increased pelleting stability" and the Nielsen reference are equally applicable to the rejections of claim 18 and the claims dependent therefrom and are incorporated herein in their entirety.

[5] See footnote 1 above.

As explained above, Nielsen does not teach a granulate having a phytase activity of at least 6000 FTU per gram and none of the references cited by the Examiner in any of the obviousness rejections mention pelleting stability or recognized that increased pelleting stability was a function of the high activity phytase-containing granulate as claimed. Moreover, the Examiner has acknowledged that neither Nielson, Ghani, Markussen, nor Haarasilta discuss pelleting stability (see Office Action dated July 27, 2007, p. 6, item 14; Final Office Action dated September 30, 2008). Accordingly, because all of the claim limitations are not taught or suggested by the references cited by the Examiner, a *prima facie* case of obviousness has not been established. The obviousness rejection should be reversed on these grounds alone.

Further as stated above, Nielsen does not teach or suggest a high activity phytase-containing granulate having phytase activity of at least 6000 FTU per gram. The Examiner acknowledges that Nielsen does not mention increased pelleting stability, does not teach extrusion of the granulate, does not teach a carrier comprising 15% (w/w) starch, does not teach at least one divalent cation, or a gel-forming or water insoluble compound (Office Action dated July 27, 2007, p. 5, item 12; p. 6, item 14).

The Examiner relies on Ghani for allegedly teaching a carrier containing 90% soy flour and 10% corn syrup (Office Action dated July 7, 2007, p. 5). However, this disclosure of Ghani does not teach or suggest a non-fibrous solid carrier which comprises at least 15% (w/w) of starch as required by the claims. In addition, the Examiner acknowledges that Ghani does not discuss pelleting stability with regard to phytase granulates (Office Action dated July 7, 2007, p. 6, item 14), does not teach phytase granulates, and does not teach a specific divalent cation (Office Action dated May 18, 2006, p. 7).

Ghani further does not teach granules prepared by extrusion. Ghani discloses gentler preparation methods such as spray-drying, fluid bed granulation or high-shear granulation (Supplemental Amendment After Final Action Under 37 C.F.R. 1.116 dated June 18, 2007). The Examiner relies on Haarasilta for providing granules made by extrusion not Ghani (Office Action dated July 7, 2007, p. 7). Therefore, Ghani does not remedy the deficiencies of Nielsen. The combination of Nielsen and Ghani does not arrive at the claimed high activity phytase-containing granulate having increased pelleting stability prepared by a process which comprises

mixing a non-fibrous solid carrier comprising at least 15% (w/w) of starch and an aqueous liquid comprising a phytase at a concentration of at least 14,000 FTU per gram of aqueous liquid to form a granulate having a phytase activity of at least 6000 FTU per gram and wherein the granulate is produced by extrusion. Furthermore, Nielsen and Ghani do not teach, suggest, or recognize that increased pelleting stability was a function of the high activity phytase-containing granulate as claimed. Because Ghani does not remedy the deficiencies of Nielsen, Nielson and Ghani, alone or in combination, do not disclose or teach all the claim limitations, and as such a *prima facie* case of obviousness has not been established for this additional reason.

Moreover as discussed above, assuming *arguendo* that a *prima facie* case of obviousness had been established, a *prima facie* case of obviousness is rebuttable by evidence that the claimed invention possesses unexpectedly advantageous or superior properties. See *KSR Int'l Co. v. Teleflex, Inc*, 127 S.Ct. 1727; 82 USPQ2d 1385 (2007), *In re Papesch*, 315 F.2d 382 (CCPA 1963). Surprisingly, the high activity phytase granulates of Appellants' invention have high phytase activity even after having been pelleted as explained above (p. 2, l. 31 through p. 3, l. 3), and as exemplified in Examples 5 and 10 (see also attached Declaration, Appendix B, at paragraphs 3 through 9 further explaining Example 5 and its teachings). For this additional reason, the obviousness rejection should be reversed.

For at least these reasons and those above for claim 19 and the claims dependent therefrom, reversal of the obviousness rejections are respectfully requested for claim 18 and the claims dependent therefrom. *See In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988) (holding that if an independent claim is nonobvious then any claim dependent therefrom is nonobvious).

C. Claims 22 and 46 Are Non-Obvious Over Nielson In View Of Ghani in further view of Markussen.

Claims 22 and 46 were rejected under 35 U.S.C. § 103(a) as being obvious over Nielsen in view of Ghani and further in view of Markussen *et al.* ("Markussen").

The explanations provided above for Nielson in view of Ghani are equally applicable to the rejections over Nielson in view of Ghani in further view of Markussen and are incorporated herein in their entirety.

Claim 22

Claim 22 depends indirectly from claim 19 adding the limitation that the hydrophobic, gel-forming or water insoluble compound comprised in the granules (as in claim 21) comprises polyvinyl alcohol (PVA) or an edible oil.

As stated above, Nielsen does not teach or suggest a high activity phytase-containing granulate having phytase activity of at least 6000 FTU per gram. The Examiner acknowledges that Nielsen does not mention increased pelleting stability, does not teach extrusion of the granulate, does not teach a carrier comprising 15% (w/w) starch, does not teach at least one divalent cation, or a gel-forming or water insoluble compound (Office Action dated July 27, 2007, p. 5, item 12; p. 6, item 14). Furthermore, Ghani does not teach or suggest a non-fibrous solid carrier which comprises at least 15% (w/w) of starch as required by the claims. In addition, the Examiner acknowledges that Ghani does not discuss pelleting stability with regard to phytase granulates (Office Action dated July 7, 2007, p. 6, item 14), does not teach phytase granulates, and does not teach a specific divalent cation (Office Action dated May 18, 2006, p. 7).

Markussen is relied on for allegedly teaching an enzyme granule which contains poylyvinyl alcohol (Office Action dated January 11, 2006). The Examiner acknowledges that Markussen does not teach phytase-containing granulates (Office Action January 11, 2006) and does not teach the level of phytase activity in the granulate (Final Office Action dated September 30, 2008). Markussen's disclosure is limited to granulates requiring a fibrous carrier (*i.e.* cellulose) and describes the cellulose as responsible for one of the advantageous properties of the disclosed granulate (*i.e.* the absence of the unwanted layer of starting material on the walls of the granulator (col. 2, ll. 14-19, 27-30, 47-55) (see Supplemental Amendment After Final Action Under 37 C.F.R. 1.116 dated June 18, 2007). Furthermore, Markussen describes granulation of enzymes as a "difficult task" that is "extremely difficult to control." (col. 1, ll. 35-30, col. 2, ll. 1-15).

Markussen does not remedy the deficiencies of Nielsen and Ghani.

Because Markussen's disclosure is limited to granulates requiring a fibrous carrier, one of skill in the art would not look to Markussen for a high activity phytase-containing granulates comprising a non-fibrous solid carrier as recited in the claims. Thus Markussen is not combinable Nielsen and Ghani.

Assuming *arguendo* that Markussen was combinable with Nielsen and Ghani, as explained above for claim 19 for the combination of Nielsen and Ghani, the combination of Nielsen, Ghani, and Markussen still does not arrive at the claimed granulate having high phytase activity of at least 6000 FTU per gram and having increased pelleting stability, the granulate comprising dried granules formed from an aqueous liquid comprising a phytase at a concentration of at least 14,000 FTU per gram of aqueous liquid and a non-fibrous solid carrier which comprises at least 15% (w/w) of starch and at least one divalent cation.

Ghani and Markussen, alone or in combination with Nielsen, do not mention pelleting stability and do not teach the level of phytase activity as also acknowledged by the Examiner. Furthermore, these references do not teach, suggest, or recognize that increased pelleting stability is a function of the high activity phytase-containing granulate as claimed. Since the Examiner relies on Nielsen for the alleged teaching of a granulate of at least 6000 FTU/gram, Ghani and Markussen do not remedy the lack of teaching of Nielsen. Since Nielson, Ghani, and Markussen, alone or in combination, do not disclose or teach all the claim limitations, a *prima facie* case of obviousness has not been established.

Further, assuming *arguendo* that a *prima facie* case of obviousness had been established, a *prima facie* case of obviousness is rebuttable by the evidence described above demonstrating unexpectedly advantageous or superior properties that the claimed invention possesses.

Claim 46

Claim 46 depends indirectly from claim 18 adding the limitation that the hydrophobic, gel-forming or water insoluble compound comprised in the granules (as in claim 45) comprises polyvinyl alcohol (PVA) or an edible oil.

As stated above, Nielsen does not teach or suggest a high activity phytase-containing granulate having phytase activity of at least 6000 FTU per gram. The Examiner acknowledges that Nielsen does not mention increased pelleting stability, does not teach extrusion of the granulate, does not teach a carrier comprising 15% (w/w) starch, does not teach at least one divalent cation, or a gel-forming or water insoluble compound (Office Action dated July 27, 2007, p. 5, item 12; p. 6, item 14). Furthermore, Ghani does not teach or suggest a non-fibrous solid carrier which comprises at least 15% (w/w) of starch as required by the claims. In addition, the Examiner acknowledges that Ghani does not discuss pelleting stability with regard to phytase granulates (Office Action dated July 7, 2007, p. 6, item 14), does not teach phytase granulates, and does not teach a specific divalent cation (Office Action dated May 18, 2006, p. 7). Ghani further does not teach granules prepared by extrusion. Ghani discloses gentler preparation methods such as spray-drying, fluid bed granulation or high-shear granulation (Supplemental Amendment After Final Action Under 37 C.F.R. 1.116 dated June 18, 2007). The Examiner relies on Haarasilta for providing granules made by extrusion not Ghani (Office Action dated July 7, 2007, p. 7).

Markussen is relied on for allegedly teaching an enzyme granule which contains poylyvinyl alcohol (Office Action dated January 11, 2006). The Examiner acknowledges that Markussen does not teach phytase-containing granulates (Office Action January 11, 2006) and does not teach the level of phytase activity in the granulate (Final Office Action dated September 30, 2008). Markussen's disclosure is limited to granulates requiring a fibrous carrier (*i.e.* cellulose) and describes the cellulose as responsible for one of the advantageous properties of the disclosed granulate (*i.e.* the absence of the unwanted layer of starting material on the walls of the granulator (col. 2, ll. 14-19, 27-30, 47-55) (Supplemental Amendment After Final Action Under 37 C.F.R. 1.116 dated June 18, 2007). Furthermore, Markussen describes granulation of enzymes as a "difficult task" that is "extremely difficult to control." (col. 1, ll. 35-30, col. 2, ll. 1-15).

Markussen does not remedy the deficiencies of Nielsen and Ghani.

Because Markussen's disclosure is limited to granulates requiring a fibrous carrier, one of skill in the art would not look to Markussen for a high activity phytase-containing granulates

comprising a non-fibrous solid carrier as recited in the claims. Thus Markussen is not combinable Nielsen and Ghani.

Assuming *arguendo* Markussen was combinable with Nielsen and Ghani, as explained above for claim 18 for the combination of Nielsen and Ghani, the combination of Nielsen, Ghani, and Markussen still does not arrive at the claimed high activity phytase-containing granulate. Ghani and Markussen, alone or in combination with Nielsen, do not mention pelleting stability and do not teach the level of phytase activity as also acknowledged by the Examiner. Furthermore, these references do not teach, suggest, or recognize that increased pelleting stability is a function of the high activity phytase-containing granulate as claimed. Since the Examiner relies on Nielsen for the alleged teaching of a granulate of at least 6000 FTU/gram, Ghani and Markussen do not remedy the lack of teaching of Nielsen. Since Nielson, Ghani, and Markussen, alone or in combination, do not disclose or teach all the claim limitations, a *prima facie* case of obviousness has not been established.

Further, assuming *arguendo* that a *prima facie* case of obviousness had been established, a *prima facie* case of obviousness is rebuttable by the evidence described above demonstrating unexpectedly advantageous or superior properties that the claimed invention possesses.

D. The Claims Are Non-Obvious Over Nielson In View Of Ghani And Further In View Of Haarasilta.

The explanations provided above for Nielson in view of Ghani are equally applicable to the rejections over Nielson in view of Ghani and further in view of Haarasilta and are incorporated herein in their entirety.

Claims 19, 21, 22, 24, 26-28, and 41-44

Claims 18-19, 21-22, 24, 26-28, 31-35, 41-46, 48, 50-52 were rejected under 35 U.S.C. 103(a) for obviousness over Nielsen in view of Ghani and further in view of Haarasilta.

As stated above, Nielsen does not teach or suggest a high activity phytase-containing granulate having phytase activity of at least 6000 FTU per gram. The Examiner acknowledges that Nielsen does not mention increased pelleting stability, does not teach extrusion of the granulate, does not teach a carrier comprising 15% (w/w) starch, does not teach at least one divalent cation, or a gel-forming or water insoluble compound (Office Action dated July 27, 2007, p. 5, item 12; p. 6, item 14). Furthermore, Ghani does not teach or suggest a non-fibrous solid carrier which comprises at least 15% (w/w) of starch as required by the claims. In addition, the Examiner acknowledges that Ghani does not discuss pelleting stability with regard to phytase granulates (Office Action dated July 7, 2007, p. 6, item 14), does not teach phytase granulates, and does not teach a specific divalent cation (Office Action dated May 18, 2006, p. 7).

The Examiner relies on Haarasilta for teaching granulates containing inorganic salts having divalent cations (Office Action dated may 18, 2006, p. 8). The purpose of the inorganic salts in the feedstuff of Haarasilta is to assist in the formation of stable granules resisting decomposition in rumen conditions. The Examiner acknowledges that the granulates of Haarasilta comprise fibrous materials. Haarasilta further discloses that their feedstuff is to include coarse feed such as fibrous hay or straw as being necessary for proper action in the rumen.

Haarasilta does not remedy the deficiencies of Nielsen and Ghani.

Resistance to decomposition in the rumen as taught by Haarasilta requires granulates to resist high acid conditions. In contrast, the present highly active granulate overcomes enzyme stability problems arising from high temperatures associated with pelleting during feed processing while retaining high enzyme activity. The skilled artisan would not look to the disclosure of granulates for resisting high acid conditions as taught by Haarisilta to apply to granulates containing enzymes which can withstand high temperatures associated with the pelleting process. The skilled artisan would additionally not look to the disclosure of granulates requiring fibrous hay or straw for proper action in the rumen or inorganic salts for decomposition stabilization as taught by Haarasilta to apply to a granulate having a high phytase activity comprising a non-fibrous solid carrier as claimed. Thus Haarasilta is not combinable with

Nielsen and Ghani and a *prima facie* case of obviousness has not been established for this addition reason.

Assuming *arguendo* Haarasilta was combinable with Nielsen and Ghani, as explained above for claim 19 for the combination of Nielsen and Ghani, the combination of Nielsen, Ghani, and Haarasilta still does not arrive at the claimed granulate. In addition, Ghani and Haarasilta, alone or in combination with Nielsen, do not mention pelleting stability and do not teach the level of phytase activity as also acknowledged by the Examiner. Furthermore, these references do not teach, suggest, or recognize that increased pelleting stability is a function of the high activity phytase-containing granulate as claimed. Since the Examiner relies on Nielsen for the alleged teaching of a granulate of at least 6000 FTU/gram, Ghani and Haarasilta do not remedy the lack of teaching of Nielsen. Since Nielson, Ghani, and Haarasilta, alone or in combination, do not disclose or teach all the claim limitations, a *prima facie* case of obviousness has not been established.

Further, assuming *arguendo* that the references were combinable and a *prima facie* case of obviousness had been established, a *prima facie* case of obviousness is rebuttable by the evidence described above demonstrating unexpectedly advantageous or superior properties that the claimed invention possesses.

For at least these reasons, reversal of the obviousness rejections are respectfully requested for claim 19 and the claims dependent therefrom. *See In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988) (holding that if an independent claim is nonobvious then any claim dependent therefrom is nonobvious).

Claims 18, 31-35, 45, 46, 48, and 50-52

Claims 18-19, 21-22, 24, 26-28, 31-35, 41-46, 48, 50-52 were rejected under 35 U.S.C. 103(a) for obviousness over Nielsen in view of Ghani and further in view of Haarasilta.

As explained above for claim 18 for the combination of Nielsen and Ghani, the combination of Nielsen, Ghani, and Haarasilta still does not arrive at the claimed high activity phytase-containing granulate having increased pelleting stability prepared by a process which comprises mixing a non-fibrous solid carrier comprising at least 15% (w/w) of starch and an

aqueous liquid comprising a phytase at a concentration of at least 14,000 FTU per gram of aqueous liquid to form a granulate having a phytase activity of at least 6000 FTU per gram and wherein the granulate is produced by extrusion.

As stated above, Nielsen does not teach or suggest a high activity phytase-containing granulate having phytase activity of at least 6000 FTU per gram. The Examiner acknowledges that Nielsen does not mention increased pelleting stability, does not teach extrusion of the granulate, does not teach a carrier comprising 15% (w/w) starch, does not teach at least one divalent cation, or a gel-forming or water insoluble compound (Office Action dated July 27, 2007, p. 5, item 12; p. 6, item 14). Furthermore, Ghani does not teach or suggest a non-fibrous solid carrier which comprises at least 15% (w/w) of starch as required by the claims. In addition, the Examiner acknowledges that Ghani does not discuss pelleting stability with regard to phytase granulates (Office Action dated July 7, 2007, p. 6, item 14), does not teach phytase granulates, and does not teach a specific divalent cation (Office Action dated May 18, 2006, p. 7). Ghani further does not teach granules prepared by extrusion.

As mentioned above, the Examiner relies on Haarasilta for teaching granulates containing inorganic salts having divalent cations (Office Action dated may 18, 2006, p. 8). The purpose of the inorganic salts in the feedstuff of Haarasilta is to assist in the formation of stable granules resisting decomposition in rumen conditions. The Examiner acknowledges that the granulates of Haarasilta comprise fibrous materials. Haarasilta further discloses that their feedstuff is to include coarse feed such as fibrous hay or straw as being necessary for proper action in the rumen.

The Examiner additionally relies on Haarasilta for providing granules made by extrusion (Office Action dated July 7, 2007, p. 7). However, the Examiner acknowledges that neither Nielsen nor Haarasilta teach the extrusion of granulates lacking fibrous materials (Office Action dated May 18, 2006, p. 6).

Resistance to decomposition in the rumen as taught by Haarasilta requires granulates to resist high acid conditions. In contrast, the present highly active granulate overcomes enzyme stability problems arising from high temperatures associated with pelleting during feed processing while retaining high enzyme activity. The skilled artisan would not look to the

disclosure of granulates for resisting high acid conditions as taught by Haarisilta to apply to granulates containing enzymes which can withstand high temperatures associated with the pelleting process. The skilled artisan would additionally not look to the disclosure of granulates requiring fibrous hay or straw for proper action in the rumen or inorganic salts for decomposition stabilization as taught by Haarasilta to apply to a granulate having a high phytase activity comprising a non-fibrous solid carrier as claimed. Thus Haarasilta is not combinable with Nielsen and Ghani and a *prima facie* case of obviousness has not been established for this addition reason.

Assuming *arguendo* Haarasilta was combinable with Nielsen and Ghani, Ghani and Haarasilta, alone or in combination with Nielsen, do not mention pelleting stability and do not teach the level of phytase activity as also acknowledged by the Examiner. These references also do not teach, suggest, or recognize that increased pelleting stability is a function of the high activity phytase-containing granulate as claimed. Since the Examiner relies on Nielsen for the alleged teaching of a granulate of at least 6000 FTU/gram, Ghani and Haarasilta do not remedy the lack of teaching of Nielsen. Since Nielson, Ghani, and Haarasilta, alone or in combination, do not disclose or teach all the claim limitations, a *prima facie* case of obviousness has not been established.

Further, assuming *arguendo* that the references were combinable and a *prima facie* case of obviousness had been established, a *prima facie* case of obviousness is rebuttable by the evidence described above demonstrating unexpectedly advantageous or superior properties that the claimed invention possesses.

For at least these reasons, reversal of the obviousness rejections are respectfully requested for claim 18 and the claims dependent therefrom. *See In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988) (holding that if an independent claim is nonobvious then any claim dependent therefrom is nonobvious).

E. Conclusion.

In sum, for the reasons discussed above, reversal of the rejections of claims 18-19, 21-22, 24, 26-28, 31-35, 41-46, 48, 50-52 is respectfully requested.

VIII. CLAIMS

A copy of the claims involved in the present appeal is attached hereto as Appendix A.

IX. EVIDENCE

A copy of the Declaration of Dr. Lutz End pursuant to 35 C.F.R. § 1.132 previously submitted with the Amendment in Response to Non-Final Action dated January 24, 2008 is attached for the Board's convenience as Appendix B.

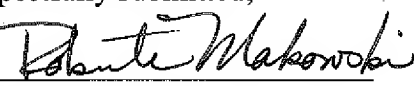
X. RELATED PROCEEDINGS

As stated in section II supra, a copy of the Board decision issued in Appeal No. 2006-0201 (U.S. Application Serial No. 10/125,272, now U.S. Patent No. 7,186,533) is provided as Appendix C. The above referenced appeal may have a bearing on the current appeal.

This Appeal Brief is filed within the two month period from the date of filing the Notice of Appeal to and including February 9, 2009 pursuant to 37 CFR § 41.37(a), with the required fee authorization pursuant to 37 CFR § 41.20(b)(2). No further fee is believed due. However, if a fee is due, please charge our Deposit Account No. 03-2775, under Order No. 12810-00682-US from which the undersigned is authorized to draw.

Dated: February 9, 2009

Respectfully submitted,

By 

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APPENDIX A

Claims Involved in the Appeal of Application Serial No. 09/089,871

1-17. (Cancelled).

18. (Previously presented) A high activity phytase-containing granulate having increased pelleting stability comprising the steps of:

(a) providing a non-fibrous solid carrier comprising at least 15% (w/w) of starch;

(b) providing an aqueous liquid comprising a phytase at a concentration of at least 14,000 FTU per gram of aqueous liquid; and

(c) mixing the solid carrier and the aqueous liquid to form a granulate having a phytase activity of at least 6000 FTU per gram;

wherein said granulate is prepared by extrusion.

19. (Previously presented) A granulate having a phytase activity of at least 6000 FTU per gram and having increased pelleting stability comprising dried granules formed from an aqueous liquid comprising a phytase at a concentration of at least 14, 000 FTU per gram of aqueous liquid and a non-fibrous solid carrier which comprises at least 15% (w/w) of starch and at least one divalent cation.

20. (Cancelled).

21. (Previously presented) A granulate according to claim 19 wherein the granules comprise one or more hydrophobic, gel-forming or water insoluble compound(s).

22. (Previously presented) The granulate according to claim 21 wherein the hydrophobic, gel-forming or water insoluble compound comprises polyvinyl alcohol (PVA) or an edible oil.

23. (Cancelled).

24. (Previously presented) The granulate according to claim 19 which additionally comprises an endo-xylanase and/or β-glucanase.

25. (Cancelled).

26. (Previously presented) The granulate according to claim 19 wherein the phytase is other than a heat tolerant (thermostable) phytase.

27. (Previously presented) The granulate according to claim 19 wherein the phytase is a fungal phytase.

28. (Previously presented) The granulate according to claim 19 wherein the fungal phytase is derived from an *Aspergillus* or *Trichoderma* species.

29.-30. (Cancelled).

31. (Previously presented) A composition comprising:

the granulate according to claim 18.

32. (Previously presented) A composition according to claim 31 which is an edible feed composition.

33. (Previously presented) A composition according to claim 31 which is an animal feed.

34. (Previously presented) A composition according to claim 31, wherein said composition comprises pellets that comprise one or more feed substance(s) or ingredient(s) mixed with said granulate.

35. (Previously presented) A composition according to claim 31 which is an animal feed, or a premix or precursor to an animal feed, and is prepared by a process that comprises mixing a phytase-containing granulate with one or more animal feed substance(s) or ingredient(s).

36-40. (Cancelled).

41. (Previously presented) A composition comprising:

a granulate according to claim 19.

42. (Previously presented) The composition according to claim 41 which is an edible feed composition.

43. (Previously presented) The composition according to claim 41 which is an animal feed.

44. (Previously presented) The composition according to claim 41, wherein said composition comprises pellets that comprise one or more feed substance(s) or ingredient(s) mixed with said granulate.

45. (Previously presented) The granulate according to claim 18 wherein the granules comprise one or more hydrophobic, gel-forming or water insoluble compound(s).

46. (Previously presented) The granulate according to claim 45 wherein the hydrophobic, gel-forming or water insoluble compound comprises polyvinyl alcohol (PVA) or an edible oil.

47. (Cancelled).

48. (Previously presented) The granulate according to claim 18 which additionally comprises an endo-xylanase and or β-glucanase.

49. (Cancelled).

50. (Previously presented) The granulate according to claim 18 wherein the phytase is other than a heat tolerant (thermostable) phytase.

51. (Previously presented) The granulate according to claim 18 wherein the phytase is a fungal phytase.

52. (Previously presented) The granulate according to claim 18 wherein the fungal phytase is derived from an *Aspergillus* or *Trichoderma* species.

APPENDIX B

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Rudolf C. BARENDSE et al.

Application No.: 09/089,871 Confirmation No.: 3289

Filed: June 4, 1998 Art Unit: 1652

For: HIGH-ACTIVITY PHYTASE COMPOSITIONS Examiner: Delia M. Ramirez, Ph.D.

DECLARATION UNDER 37 C.F.R. § 1.132

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Madam:

1. I, Dr. Lutz End, am an expert in the field of chemical and pharmaceutical formulation, and was at the time of the invention. I am presently employed as Head of Formulation and Nutrition R&D in the Care Chemicals Division at BASF SE (formerly known as the Fine Chemicals Division of BASF Aktiengesellschaft). My resume is attached as documentation of my credentials (**Exhibit A**).

2. This Declaration is being filed in response to the Examiner's concerns regarding the meaning of the term "increased pelleting stability" that were raised in the Office Action dated July 27, 2007 ("the OA"). First, the Examiner expressed concern that the term is "unclear and confusing in the absence of a basis for comparison (i.e., increased with respect to what)" (the OA at p. 3, ¶ 4). Second, the Examiner seems to believe that a person skilled in the art at the time of the invention "would interpret the term 'pelleting stability' to refer to the structural stability of the pellet under different conditions (e.g., temperature, pressure, pH, etc.)" (Id.) It appears from the Office Action that the Examiner did not understand the technical disclosure in Example 5 of the specification and consequently could not determine the intended meaning of the term "pelleting stability."

3. I hereby declare that the skilled artisan, at the time of the invention, using the teachings of the specification and the knowledge known to the skilled artisan, would have understood that the term "pelleting stability" was intended to refer to residual phytase activity in the pellet after the pelleting process, and not to the structural stability of the pellet itself.

4. To illustrate the state of the art at the time of the invention, the Examiner is first referred to the text of the instant specification as published (US 2002/0034798 A1), specifically to Example 5 entitled "High Activity Phytase Stability Tests" on pages 7-8 (paras. **[0114]** – **[0127]**).

5. The preamble of Example 5 clearly states that "[t]o demonstrate that a higher enzyme concentration (in granules made using the high activity phytase liquid) gives a higher pelleting stability, granulates with an increasing enzyme concentration were made and the pelleting stability of these samples were tested" (para. **[0115]**).

6. The descriptions of Comparative Samples A, B, C indicate that the three enzyme granulates had pre-pelleting phytase activities of 610 FTU/g, 4170 FTU/g and 6830 FTU/g, respectively (see paras. **[0116]** - **[0124]**).

7. The final section of Example 5 is entitled "Comparison of pelleting stabilities." The section states that the enzyme granulates A, B and C were mixed with a feed premix at different mixing ratios, pre-treated by steam injection to give a temperature rise to 75°C, after which the mixtures were pelleted in a pelleting machine to obtain the feed pellets at a temperature of 82°C, which were subsequently dried. The section further explains that this process is typical for the feed industry to obtain feed pellets (see para. **[0126]**).

8. After the pellets were dried, the enzyme activity was measured again (data not shown), and the post-pelleting yield was calculated by comparing the residual phytase activity of each sample with corresponding pre-pelleting activity adjusted for the different mixing ratios with the feed premix. The resulting post pelleting phytase activity yields are summarized in Table 2, which shows that the low-phytase Comparative Sample A had a less than 17% yield, whereas the high-phytase Comparative Samples B and C had significantly higher yields of 37% and 48%,

respectively. Accordingly, Applicants conclude that "the two granules with the highest enzyme concentration had much higher pelleting stability" (para. **[0127]**).

9. It is important to note that structural stability of the pellets is not discussed at all in Example 5, whereas all of the discussion focuses exclusively on phytase activity. Therefore, the only reasonable conclusion that could have been made by a skilled artisan at the time of the invention is that the higher pelleting stability contemplated by the present invention means a higher yield of residual phytase activity after pelleting, and not higher structural stability of the pellets.

10. To further illustrate the state of the art at the time of the invention, the Examiner is next referred to several prior art references discussing issues relating to pelleting stability.

11. The problem of post-pelleting phytase performance was recognized as early as 1990, when Simons wrote:

> "The pelleting experiments with feed to which microbial phytase had been added showed significant inactivation of phytase activity when temperatures of the pellets after pelleting exceeded 84° C..." P.C.M. Simons, et al., Improvement of Phosphorus Availability by Microbial Phytase in Broilers and Pigs, *Br. J. Nutr.* 1990, 64:525-540, at p.537 (**Exhibit B**).

12. In 1993, Cowan referred to enzyme stability in the context of feed pelleting:

> "At a pre-pelleting conditioning temperature of 65° C, a commercial enzyme absorbed to its carrier is completely *stable*. However, as the conditioning temperature increases, the enzyme is inactivated until at 75° C the residual activity is about 30% of the starting level." W.D. Cowan, The Stability of Enzymes in Animal Feeds, *Feed Intl.* 1993, 14(4):22-25, at p. 23 (**Exhibit C**).

13. In the same year, Gadient also remarked that:

> "hydrothermal processes, such as pelleting, extrusion and expansion, have been recognized as potentially destructive for... phytase." M. Gadient, et al., Experiences with Enzymes in Feed Manufacturing, *in Proc. 1st Symp. on Enzymes in Animal Nutrition*, Kartause Ittingen, Switzerland, Oct. 13-16, 1993, 255-262, at p. 255 (**Exhibit D**).

14. Similarly, in 1993 Nunes wrote:

"The resistance of endogenous phytase and eventually that of the added one to the pelleting temperature appeared as an important question... It appeared that steam-pelleting at temperatures higher that 60° C strongly reduced phytase activity. This was particularly marked for temperatures higher than 75° C. When pelleting at 80° C the recovered phytase activity represented about 50% of the endogenous one demonstrating inactivation of both enzymatic activities... Thus, with the aim of phytase preservation in pig feed technological precautions should be taken when using steam-pelleting." C.S. Nunes, Evaluation of Phytase Resistance in Swine Diets to Different Pelleting Temperatures, *in Proc. 1st Symp. on Enzymes in Animal Nutrition*, Kartause Ittingen, Switzerland, Oct. 13-16, 1993, 269-271 **(Exhibit E)**.

15. Consistent with the earlier reports, in 1995 Ravindran noted:

"High temperatures employed during ingredient processing or during pelleting of diets can also influence the native phytase activity of plant ingredients. Plant phytase activity is not altered by such treatments at temperatures between 47° and 62° C, but higher temperatures (70-80° C) can cause partial or total inactivation." V. Ravindran, et al., Phytates: Occurrence, Bioavailability and Implications in Poultry Nutrition, *Poult. Avian Biol. Rev.* 1995, 6(2):125-143, at p. 129 **(Exhibit F)**.

16. In 1997, Spring used the term "stability curve" in the context of feed pelleting:

"Enzymes are susceptible to hydrothermal treatments as applied in pelleting, expansion and extrusion. It appears that each enzyme product has a specific '*stability curve*' and a critical temperature point at which enzyme losses start to accelerate." W.G. Spring, et al., Application of Enzymes in Compound Feeds, *CIHEAM – Options Mediterraneennes* 1997, 26:175-179, at p. 176 **(Exhibit G)**.

17. In 1997, Esteve-Garcia also wrote about enzyme stability during pelleting:

"*Stability* of enzymes during the pelleting process has been a cause for concern." E. Esteve-Garcia, et al., Bioefficacy of Enzyme Preparations Containing β-Glucanase and Xylanase Activities in Broiler Diets Based on Barley or Wheat, in Combination with Flavomycin, *Poult. Sci.* 1997, 76:1728-1737, at p. 1728 **(Exhibit H)**.

18. Finally, in 1998, the year of the present invention, Wyss specifically used the term "pelleting stability":

> "Enzymes that are used in animal feed supplements should be able to withstand temperatures of 60° to 90° C, which may be reached during the feed pelleting process... These findings confirm that *A. niger* pH 2.5 acid phosphatase is irreversibly inactivated at temperatures above 80° C and that the capacity of *A. fumigatus* phytase to refold properly after heat denaturation may favorably affect its *pelleting stability*." M. Wyss, et al., Comparison of the Thermostability Properties of Three Acid Phosphatases from Molds: *Aspergillus fumigatus* Phytase, *A. niger* Phytase, and *A. niger* pH 2.5 Acid Phosphatase, *Appl. Envir. Microbiol.* 1998, 64(11):4446-4451, at p. 4446, abstract; see also p. 4450 (**Exhibit I**).

19. Thus, based on the prior art literature, there is a clear sense that each enzyme has its own pattern of thermal inactivation as a result of feed pelleting, also known as a "stability curve". Any modifications to the enzyme itself and/or to the process of granulation that have a tendency to shift the stability curve to the right, i.e., toward a higher temperature tolerance, would be understood by a skilled artisan to result in an "increased pelleting stability" as recited in claims 18 and 19 of the present application.

20. Accordingly, based on the teachings of the specification and the knowledge and methods known at the time of the invention, the skilled artisan would have appreciated that the term "increased pelleting stability" was intended to refer to a higher than normal post-pelleting phytase activity in the pellet, and not to the structural stability of the pellet itself.

21. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

Dated: January 22, 2008

Lutz End, Ph.D.

APPENDIX C

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte CARL SIDONIUS MARIA ANDELA and
AUGUSTINUS BERNARDUS MARIA KLEIN HOLKENBORG

Appeal No. 2006-0201
Application No. 10/125,272

ON BRIEF

Before MILLS, GRIMES, and GREEN, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims to a method of making enzyme-containing granules. The examiner has rejected the claims as anticipated by or obvious in view of the prior art. We have jurisdiction under 35 U.S.C. § 134. Because the examiner has not adequately explained how the cited references teach or suggest a process that meets all the limitations of the present claims, we reverse all of the rejections.

Background

"The use of various enzymes in animal, e.g. livestock, feed has become almost common practice." Specification, page 1. "Dry enzyme formulations may be added to the feed before pelleting and therefore are subjected to heat-inactivation during

pelleting. Preferred manufacturing protocols in the feed industry involve steam pelleting where the feed is subjected to steam injection(s) prior to pelleting, a process called conditioning. . . . During this conditioning process temperatures may rise to 60-95°C. The combined effect of high moisture content and high temperature is detrimental to most enzymes." Pages 1-2.

The specification discloses "a process for the preparation of an enzyme-containing granulate suitable for use in an animal feed, the process comprising processing an enzyme, a solid carrier, optionally additives and water . . . to obtain enzyme-containing granules, drying the granules, and coating the dried granules with polyethylene glycol." Page 3.

The specification reports that coating the granules with polyethylene glycol (PEG) "protect[s] against the formation of dust" and "provide[s] a good pelleting stability of the granule"; i.e., results in less loss of enzyme activity during pelleting. Page 4, lines 1-2 and 7-8. Moreover, granules coated with PEG dissolve twenty times faster than granules with a fat-type coating, and "[a] short dissolution time significantly improves the bioavailability of the enzyme to the animal." Page 4, lines 3-7.

Discussion

1. Claim construction

Claims 1 and 3-36 are on appeal. Claim 1 is the only independent claim and reads as follows:

> 1. A process for the preparation of an enzyme-containing granulate suitable for use in animal feed, the process comprising:
>
> (a) mixing a feed enzyme, a solid carrier, water, and at least one additive in an effective amount;

(b) mechanically processing the mixture obtained in (a), simultaneously with or subsequently to the mixing, to obtain enzyme-containing granules;

(c) drying the granules; and

(d) coating the granules obtained in (c) with polyethylene glycol, wherein the polyethylene glycol has a molecular weight ranging from 6,000 to 20,000 Dalton, the granules obtained in (d) having 1) a dissolution time shorter that granules coated with oil or fat, and 2) a pelleting stability greater than uncoated granules.

The preamble of claim 1 states that the claimed process is for preparing granules "suitable for use in animal feed." "[A] claim preamble has the import that the claim as a whole suggests for it. In other words, when the claim drafter chooses to use both the preamble and the body to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one the patent protects." Bell Commc'ns Research Inc. v. Vitalink Commc'ns Corp., 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). We interpret the preamble of claim 1 to limit the potential components of the granules to those that are compatible with feeding the resulting granules to an animal. The claim however, is not limited to a method of making granules that are only suitable for use in animal feed.

The method of claim 1 comprises mixing water, a solid carrier, a feed enzyme, and "at least one additive." The specification states that "[t]he solid carrier to be used to prepare the granulate . . . is a powder which can be compacted into a granule[,] . . . preferably ha[ving] an average particle size ranging between 5 and 20 µm." Page 5, lines 1-4. "Feed enzymes include: phosphatases . . . ; carbohydrases . . .; [and] proteases . . . ," among others. Specification, page 8, lines 1-9. Suitable additives

include water-soluble inorganic salts, "hydrophobic, gel-forming or slowly dissolving compounds," and trehalose. Page 6, lines 3-27.

Thus, the process of claim 1 requires mixing water, an enzyme (e.g., a phosphatase or a protease), a "powder which can be compacted into a granule," and an additive; mechanically processing the mixture to obtain granules; drying the granules and coating them with PEG having a molecular weight of 6000 to 20,000 Daltons. Claim 1 also states that the resulting granules have "a dissolution time shorter than [that of] granules coated with oil or fat, and . . . a pelleting stability greater than uncoated granules."

2. Anticipation

The examiner rejected claims 1, 5, 7, 9, 12, 14, 15, 19, 20, 23, 31, and 34-36 under 35 U.S.C. § 102(e) as anticipated by De Lima,[1] reasoning that

> [t]he patent teaches making an enzyme containing granulate suitable for use in animal feed. The patent teaches mixing a feed enzyme, a solid carrier, water and at least one additive. The patent then mechanically processes the mixture to form the granules, dries them and then coats the granulates with polyethylene glycol (PEG).

Examiner's Answer, page 5.

Appellants argue that the reference does not identically disclose the claimed process because, among other things, "whereas De[ ]Lima begins with a granular core particle, Appellants' invention begins with a mixture that is processed into a granule." Appeal Brief, page 11. Appellants reason that "[t]he core in De[ ]Lima differs from the solid carrier in Appellants' claim 1. . . . De[ ]Lima teaches that its carrier particles

[1] De Lima et al., U.S. Patent 6,136,772, issued October 24, 2000.

preferably have relatively high physical strength. . . . In contrast, Appellants' solid carrier is a 'powder which can be compacted into a granule.'" Id.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). See also Gechter v. Davidson, 116 F.3d 1454, 1460, 43 USPQ2d 1030, 1035 (Fed. Cir. 1997) ("[T]o hold that a prior art reference anticipates a claim, the Board must expressly find that every limitation in the claim was identically shown in the single reference.").

In this case, the claims require mixing an enzyme with "a powder which can be compacted into a granule," and mechanically processing the mixture to obtain granules. The process described by De Lima, on the other hand, begins with "absorbent cores" and then contacts them with an enzyme-containing liquid. See, e.g., column 2, lines 22-29: "a process for producing enzyme-containing granules from absorbent cores, the process comprising: (a) contacting absorbent cores . . . with a liquid medium containing an enzyme in dissolved and/or dispersed form." The disclosed process therefore does not involve mixing an enzyme with a solid carrier as defined in the instant specification – "a powder which can be compacted into a granule" – and processing to produce granules.

The examiner responded to Appellants' argument by pointing to De Lima's working examples: "De Lima very clearly teaches that the compositions are **formulated** as granulates not starting with a granulate. Appellant does the same thing as De Lima, appellant also formulates a granulate by mixing the enzyme, carrier, water and an

additive together to form the granulate which is exactly what De Lima also teaches, see examples of De Lima." Examiner's Answer, page 11.

We have reviewed the working examples described by De Lima and find none that include combining a powder that can be compacted into a granule with an enzyme and processing to produce granules. On the contrary, De Lima's examples begin with granular starch cores (see, e.g., column 24, lines 15 and 65). The examiner has pointed to no specific example in De Lima that begins with a powder that is combined with water, an enzyme, and an additive, and processed into granules.

Because the process taught by De Lima does not meet all the limitations of claim 1, we reverse the rejection under 35 U.S.C. § 102(e).

3. Obviousness based on De Lima and Yamada

The examiner rejected claims 1 and 3-36 under 35 U.S.C. § 103 on the basis that the claimed process would have been obvious to those of ordinary skill in the art based on the disclosures of De Lima and Yamada.[2] The examiner characterized De Lima as teaching the process defined in claim 1, although he acknowledged that De Lima "does not teach using the specific amounts of components, such as trehalose or zinc sulfate as the additive, etc." Examiner's Answer, page 5.

The examiner characterized Yamada as "teach[ing] that granular solid enzyme preparations are stabilized by using trehalose and zinc sulfate," and concluded that "[i]t would have been obvious to one of ordinary skill in the art to use trehalose or zinc sulfate instead of PVA as the additive in the enzyme granulate of De Lima since

[2] Yamada et al., EP 501375 A1, published September 2, 1992

[Yamada] teaches that trehalose and zinc sulfate are both good enzyme stabilizers." Id., page 6.

Appellants argue that "as . . . discussed above, the De[ ]Lima and [Yamada] processes are quite different from Appellants' process. The granules are formed in De[ ]Lima by spraying and mixing an aqueous enzyme onto a preformed core. The granules are formed in [Yamada] by mixing a disaccharide and an enzyme and spray drying." Appeal Brief, page 13.

We agree with Appellants that Yamada does not remedy the deficiency of De Lima. Specifically, the examiner has not adequately explained why Yamada's disclosure – stabilizing an enzyme by mixing it with a disaccharide before spray-drying – would have led a person of ordinary skill in the art to modify De Lima's disclosed process – coating pre-formed cores with an enzyme-containing liquid – in such a way as to result in the process defined by claim 1.

"In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant." In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). Because the examiner has not adequately explained why the cited references would have suggested the process of claim 1 to a person of ordinary skill in the art, he has not established a prima facie case of obviousness. We therefore reverse the rejection under 35 U.S.C. § 103.

4. Other obviousness rejections

The examiner also rejected claims 1 and 3-36 under 35 U.S.C. § 103, based on the following combinations of references:

- Barendse[3] or Harz,[4] combined with De Lima and Yamada;
- Olsen[5] or Bisgard-Frantzen,[6] combined with Yamada; and
- WO 98/54980[7] or WO 98/55599,[8] combined with De Lima and Yamada.

The examiner characterized the additional references as follows:

- "Barendse and Harz each teach an enzyme containing granulate" (Examiner's Answer, page 7);
- "Olsen and Bisgard[-Frantzen] each teach making the claimed enzyme containing granulate since they teach enzymes mixed with water, a carrier and an additive" (id., page 8); and
- "The WO's each teach making the claimed enzyme containing granulate" (id., page 9).

We have reviewed the cited references but neither the examiner's explanation of the rejection nor our review of the reference has revealed any disclosure that would have suggested a process meeting all the limitations of the method of instant claim 1. None of the additional references make up for the deficiencies of De Lima and Yamada, discussed above. We therefore reverse the rejections based on Barendse or Harz,

[3] Barendse et al., U.S. Patent 5,827,709, issued October 27, 1998
[4] Harz et al., U.S. Patent 5,972,669, issued October 26, 1999
[5] Olsen et al., U.S. Patent 5,856,451, issued January 5, 1999
[6] Bisgard-Frantzen et al., U.S. Patent 6,106,828, issued August 22, 2000
[7] Barendse et al., WO 98/54980, published December 10, 1998
[8] Barendse et al., WO 98/55599, published December 10, 1998

combined with De Lima and Yamada; Olsen or Bisgard-Frantzen, combined with Yamada; and WO 98/54980 or WO 98/55599, combined with De Lima and Yamada.

Summary

The examiner has not adequately shown that De Lima disclosed, or that the cited references collectively would have suggested, the process defined by claim 1 on appeal. We therefore reverse all of the rejections.

REVERSED

Demetra J. Mills
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

Lora M. Green
Administrative Patent Judge

) BOARD OF PATENT
) APPEALS AND
) INTERFERENCES

EG/jlb